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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,498	10/22/2003	Henning Ueck	0288-029P/JAB	9669

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,498	UECK, HENNING	
	Examiner	Art Unit	
	HERBERT J. LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Aug 22, 2003, Oct 14, 2003 , Sep 7,2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-22-03;10-14-03,9-7-04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

1. Receipt is acknowledged of the preliminary amendment filed August 22, 2003 and the three prior art information disclosure statements file August 22, 2003, October 14, 2003 and September 07, 2004.

2. This application is a divisonals of Ser. No. 10/088,469 filed March 15, 2002, now U.S. Patent 6,800,305 which was a 371 of PCT/EP00/08903 09/12/2000 with claimed benefit to foreign DE 299 16 014.9 filed September 16, 1999.

3. Claims 1-13 are present in this application.

4. Claims 6 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. U.S 6,800,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to the same combination capsules for these two claims as noted below:

> 1. A pharmaceutical composition for oral administration in the form of a hard or soft gelatin capsule comprising Eucalyptus oil and orange oil, wherein the ratio by weight of Eucalyptus oil to orange oil is between 1:10 and 10:1.
>
> 3. The pharmaceutical composition of claim 1, wherein the content of Eucalyptus oil and orange oil is 1 to 80 percent by weight.
> 4. The pharmaceutical composition of claim 1, wherein the content of Eucalyptus oil and orange oil is 10 to 75 percent by weight.
> 5. The pharmaceutical composition of claim 1, wherein the content of

Eucalyptus oil and orange oil is 40 to 70 percent by weight.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. In addition, Claims 6 and 7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims of prior U.S. Patent No. 6,800,305 This is a double patenting rejection.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 4-13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple claim. See MPEP § 608.01(n).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

B. In the present instance, claim 7 recites the broad recitation of a

range 1-80 percent , and the claim also recites 10-75 as well as 40-70 percent which is the narrower statement of the range/limitation.

Also, in the present instance, claim 9 contains 0.1 to 10 percent followed by 0.3 to 7 percent and 0.5 to 3 percent.

II. In addition both claims 7 and 9, contain the following words:

a. "preferably" and "particularly" –claim 7

b, "preferably" and "especially" –claim 9.

Each of the words is considered to render the claim indefinite because it is unclear whether the limitation(s) following the word is part of the claimed invention. See MPEP § 2173.05(d).

Applicant is requested to delete the phrases containing the objectionable word which may be placed in a separate dependent claim for each of the desired limitations to overcome the above rejections.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-5 and 8-13 are rejected under 35 U.S.C. 102(b) as anticipated by

i.> Dubinskii RU2038092, Linsig et al CH688787 ;

ii.> Weise U.S. 6,444,238, priority to 1999 patent application US-142233P filed July 2, 1999) ;

iii. Stewart, U.S. 5,686,074.

iv. Abstract FR2504551, Dehais C.

Each of the references teaches a composition which is within the scope of the claims:

i.> Dubinskii teaches pharmaceutical compositions containing orange oil in combination with eucalyptus oil as well as containing additional inert ingredients which is within the scope of claims 1, 4 and 8.

ii.> Weise teaches the following composition which anticipates claims 1-5 and 8-13 as noted by the following disclosure

> The pain relief composition is substantially a mixture of essential oils. Essential oils used in preparing the pain relief composition of the present invention include aloe vera, peppermint, lemon, orange, and rosemary oils. The concentration of aloe vera oil is between about 10 and 18 percent by weight and preferably between about 13 and 16 percent by weight. **The concentration of eucalyptus oil is between about 0.5 and 5 percent by weight and preferably between about 1 and 3 percent by weight.** The concentration of lemon oil is between about 0.5 and 5.0 percent by weight and preferably about 1 and 3 percent by weight. **The concentration of orange oil is between about 0.5 and 5.0 percent by weight and preferably about 1 and 3 percent by weight.**

iii.> Stewart, U.S. 5,686,074 which teaches the following compositions:

> A preferred embodiment of the composition is for the treatment of an allergic contact dermatitis caused by an exposure of human skin to urushiol. In this embodiment the composition comprises 3.8 volume percent linseed oil, 3.8 volume percent alum powder, 90.6 volume percent cornstarch, **1 volume percent eucalyptus oil**, and **0.5 volume percent orange oil.**

The combination and ratio as well the additional ingredients anticipates claims 1-5 and 8-13.

iv. The Dehais abstract submitted by Applicant teaches a pharmaceutical composition containing Eucalpytus globus 1.5 % (15 ml) with orange oil 1.5% (15 ml) which combination anticipates claims 1, 2, 4 and 11-12.

v. BARRIER BIOTECH LIM, WO/99/27793 teaches a composition containing both orange oil and eucalyptus oil on pages 16-17, Example 7 which pharmaceutical composition anticipates claims 1, 2, 4, 5 and 11-12.

or, in the alternative,

Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as obvious over

i.> Dubinskii RU2038092, Linsig et al CH688787 ;

ii.> Weise U.S. 6,444,238, priority to 1999 patent application US-142233P filed July 2, 1999) ;

iii. Stewart, U.S. 5,686,074.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Dubinskii does not disclose the specific ratio of the two ingredients. However, it would have been would have been prima facie obvious for one of ordinary skilled in the art to adjust the weight ratio of the two ingredients of Dubinskii RU2038092 from 3:1 to 2:1 absent a criticality of the ratios of the two ingredients.

If there are any differences with respect to the percentages, ranges or the form of the compositions of ii Weise or iii.Stewart, these differences would have been prima facie absent a showing of unexpected or unobvious data.

8. **No claim is allowed.**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
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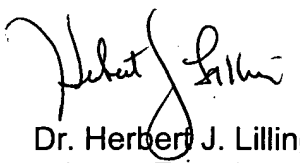
Art Unit **1651**
June 28, 2005



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651